

510(k) SUMMARY

OCT 23 1996

27 March, 1996

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PRODUCT NAMES

Device name: AS/3TM Light Monitor

Common name: Hemodynamic measurement device

DESCRIPTION OF THE DEVICE

AS/3 Light Monitor is a portable patient monitor which measures ECG, 2 invasive blood pressures, oxygen saturation SpO₂, 2 temperatures and non-invasive blood pressure NIBP. The measurement technics are similar to the AS/3 Compact Monitor with ESTP module and NIBP module. See section 3 for details.

AS/3 Light Monitor will be available in two following configurations:

LM which measures ECG, SpO₂, 1 temperature and NIBP and

LMP which measures ECG, SpO₂, 2 invasive blood pressures, 2 temperatures and NIBP.

The monitor can be driven with battery or with mains power.

INTENDED USE

AS/3 Light Monitor is intended for stationary and mobile indoor monitoring of a patient's vital signs.

SUBSTANTIAL EQUIVALENCE

In terms of overall functions and parameters measured, the AS/3TM Light Monitor is substantially equivalent in safety and effectiveness to Datex AS/3TM Compact Monitor with ESTP and NIBP modules.

Measurement parameters are the same as in Datex AS/3™ Compact Monitor with ESTP and NIBP modules. Measurement units are redesigned, but measurement technics and algorithms are the same.

The specifications of the monitors were compared and AS/3™ Light Monitor was tested against the specifications. The results showed that AS/3™ Light Monitor is substantially equivalent with AS/3™ Compact Monitor.